



Trends-in-Medicine

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Quick Pulse

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REFRACTIVE SURGERY UPDATE

Eighteen refractive surgeons, representing a range of practices – from large to small and from academic to commercial chains – as well as two industry experts were interviewed to check on trends in the industry. They were definitely upbeat and positive.

LASIK PROCEDURE VOLUME

Historically, January is the strongest month of the year for many refractive surgeons, and January 2004 was no exception. The question has been whether the surge in procedures would fizzle out, but the doctors interviewed agreed that the pickup is continuing. A Texas doctor said, “Usually we see a big peak in January, but this year, it has really maintained throughout the year.” A West Coast doctor said, “Each month is improving because of patient confidence in wavefront LASIK.”

On average, sources said their June 2004 procedure volume is:

- Up 5% from the monthly average for the first quarter of 2004.
- Up 8% over May 2004. However, this may be a little aggressive since several sources said May was an exceptionally good month, and it wouldn't be surprising to see June volume a little lower than May. A California surgeon said, “May (2004) was the best month ever, and June is down 15%-18% from that, so we are back to the normal average.”
- Up 15% over June 2003.

Industry expert Dave Harmon of Market Scope (www.mktsc.com) thinks these estimates could be a little high. His sources suggest that a year-to-year increase in the high single digits or low double digits might be more accurate. He said, “No one is saying they are down compared to 1Q04 or last year...It is just a question of how much they are up.”

In many parts of the country, surgeons have traditionally experienced a “summer slowdown” in procedures, but most sources said that is not happening this year. A Michigan doctor said, “I think volume will hold at the current level.” A Florida doctor said, “I don't expect a slowdown, but that's because I'm getting a new laser.” An Illinois doctor said, “We are in a mall, and we don't usually slow down in summer. Our busiest months are December and January and then from June to the end of the year.” A California doctor added, “July appears to be booking up well. July-September and November have historically been slower months, but it doesn't look like July will be slow this year.”

Harmon expects a summer slowdown compared to the first five months of the year, but he is predicting that 2004 summer procedure volume will be higher than last year. He said, "I'm hearing the book looks good, and I expect this to be a better July than last year. The summer should be way up compared to last year, probably in the range of 8%-14%."

Overall, sources estimated that procedure volume for 2004 will end up an average of 19% ahead of 2003, driven mostly by a combination of custom ablation and a strong economy.

- *Midwest*: "We had a very quiet first half of the year, but we expect a busier second half – driven by a combination of the economy and custom cornea."
- *Texas*: "It is the economy and not custom cornea that is driving procedures. What we see now is a higher percentage of people financing the surgery. A lot of people are willing to make monthly payments on a home, a car, and this, which is a smaller payment. And they don't care what the interest rate is. We are now getting more mainstream people who want a change in lifestyle. They don't have the cash, but they are willing to use their credit card."
- *California*: "The increase in procedures is due to a combination of (1) the economy, (2) a collective sense of familiarity with LASIK, which is seen increasingly as a more acceptable option to contact lenses or glasses, and (3) the world economy coming back. What started in January is continuing."
- *Florida*: "I'm seeing a ton of referrals from past patients. A lot of people were sitting on the sidelines and waiting for new technology...I'm in a big group, but we don't do any advertising at all. We have a zero advertising budget...but our volume will be up 10%-20%, and personally I will be up about 30%."
- *West Coast*: "We are 14% ahead of where we were at this point last year...and I'm thinking by the end of the year we probably will get an increase of 10%-15% over last year."

Harmon indicated he may have to revise his estimate for 2004 soon. About a month ago, his forecast was for 1.31 million procedures in 2004, up from 1.15 million in 2003, a 14% increase. He said, "The latest consumer confidence figures were over 100, and that's the first time that's happened in three years. My model is heavily based on consumer confidence. It says that for every one point gain in consumer confidence, you have about 3,000 additional surgeries per quarter in the U.S., above what is normally expected. The consumer confidence index has soared 10 points in the last three months, and that means 30,000 additional procedures. My model had assumed that consumer confidence would hang in the mid-90s for the balance of the year. So, we may see better numbers for the year than I've been projecting...Maybe 14% is too low, and 19% is not unreasonable."

Irving Arons (www.expertsinternational.com/arons) of Spectrum Consulting agrees, "Based on the increase in the consumer confidence index, it is very likely the numbers predicted earlier for 2004 are too low, and the increase in procedure volume will be more than predicted. It could be as high as 15%-20%."

CUSTOM ABLATION

Sources estimated that they do custom ablation – with Alcon's CustomCornea, Visx's CustomVue, or Bausch & Lomb's Zyoptix – on an average of 45% of their patients, but there is a big difference among practices.

- 38% of sources do custom ablation on ≤30% of their patients. A Texas doctor said, "I really reserve it for people with significant aberrations." A California doctor said, "Wavefront was a great way to divert attention from the real reason for glare and halo – which is mismatched treatment-to-pupil size...Laser companies couldn't sell pupil tracking as a value-added feature, but they could sell wavefront."
- 31% of sources do custom ablation on 45%-60% of their patients.
- 31% of sources do custom ablation on 70%-75% of their patients. A Florida surgeon said, "I do custom cornea on everyone who is eligible, which is about 70% of patients. I can't do custom cornea for monovision. Alcon/Autonomous just now got software for that, and Visx can only change up or down half a diopter. So you can't do real monotherapy with custom cornea." A Midwest doctor said, "I do custom cornea on 100% of capable patients, which is about 75% overall. We do custom PRK on thin corneas."

On June 29, 2004, the FDA approved an expanded treatment range for Alcon's CustomCornea on the LadarVision laser: myopia up to -8.0 diopters (up from -7.0) and astigmatism up to -4.0 diopters (up from -0.5). Alcon estimates that surgeons will now be able to use CustomCornea for more than 90% of myopic LASIK patients. Alcon is conducting clinical trials to get expanded approval for the use of CustomCornea for (a) hyperopia with and without astigmatism and (b) special conditions such as pre-existing night vision problems and post-LASIK complications. Arons said, "This approval definitely will expand the use of custom ablation. Alcon only has about 20% of the laser market, but the doctors with those machines will be able to do more patients, and that will give the market a boost."

Nearly all sources predicted that use of custom ablation would grow over the next six months, particularly as the approved ranges expand, to an average of 58% of procedures. A California surgeon said, "Usage will go up with the increase in the range for astigmatism with the LadarVision." Another West Coast surgeon said, "Usage will increase as the ranges

are expanded.” A third source said, “Usage will increase because a new procedure is being perfected called Epi-LASIK. It will be the best way to get better than 20/20 vision out of custom cornea.”

Epi-LASIK uses a special, blunt blade and suction to separate the epithelial sheet mechanically without the use of alcohol. A dry custom contact lens is then placed over the flap, which sticks to the lens, making it easy to lift and flip over nasally. After laser ablation, the flap (with the contact lens) is placed back on the eye.

PRICING

On average, sources said they charge \$1,992 per eye for LASIK, though several doctors charge more if they use an IntraLase keratome. The range is \$1,500 to \$2,495. All but one source charge extra for custom ablation, and the average additional charge for custom ablation is \$390.

Most doctors in the U.S., like these sources, are continuing to have dual pricing – one price with custom ablation and another without it, but a small but growing number of doctors have decided to charge the same fee whether patients get custom ablation or not. An Illinois surgeon explained why he has gone to flat pricing: “Initially, we had two-tiered pricing, and we found we were doing more enhancements for classic LASIK. So, now we charge one price for all. That only makes sense...Most good refractive surgeons believe custom ablation is better, so why offer inferior quality care?”

Market Scope’s Harmon agreed there is a movement to flat pricing – but in the premium end of the market only. He said, “These high end surgeons are trying to differentiate themselves from everyone else, and the message of ‘only the best’ resonates with a certain segment of the population, a large segment...The strategy works well for those doctors.”

Most patients are getting custom (wavefront) diagnostics, whether they get custom ablation or not, but none of these sources is advertising custom ablation and doing primarily traditional LASIK. A Texas doctor said, “All patients get custom diagnostics. Patients don’t know they have high aberrations, but I don’t charge extra for the diagnostics.” A Midwest doctor said, “Everyone gets wavefront, and we don’t charge extra for it.” A California doctor said, “In markets where there are multiple providers, which is most markets now, some people choose to distinguish themselves by saying we only do wavefront. It’s a kind of arrogance and a way to justify their price point. It is asserting that wavefront has greater value...That strategy works for some of the high priced providers in a market...Perception of value is the key... But I don’t recommend custom cornea for the garden variety myope (– 2.0 diopters).”

OTHER REFRACTIVE PROCEDURES

PRK

Almost half the sources said they have seen a slight uptick in PRK.

- A California doctor commented, “I think there is a little up tick. I’ve seen it in my practice. In part, it is young surgeons who consider themselves invincible and bulletproof. After a few cases of significant early or late LASIK complications, they get a little less aggressive and dial back the indications for LASIK and start offering PRK as a not unreasonable alternative. Also, PRK is an excellent procedure.”
- A Florida surgeon said, “I’m doing more PRK because thinner corneas are going more to PRK. Anything at all funky I’ll PRK.”
- Another doctor said, “We will be doing more Epi-LASIK when the new Epi-LASIK keratome (which Novartis/CibaVision recently sold to Norwood Abbey) gets 510K approval from the FDA.”
- A Midwest doctor said, “There is a big-time resurgence in PRK. It is a very good procedure...The results with custom PRK are awesome. All the patients who were non-candidates for LASIK because they had thin corneas are now turning out really well.”
- Another surgeon said, “There definitely is a big increase in PRK because people (surgeons) are getting less aggressive with LASIK.”
- Dave Harmon added, “I’m not seeing a drop in microkeratome usage, and if there were a large shift to surface ablation, it would show up there.” NOTE: Custom PRK is an off-label procedure.

LASEK (laser epithelial keratomileusis) also is seeing an increase in some practices. This is a modified form of PRK in which the outer layer of the cornea (the epithelium) is loosened (not removed) and then folded back so the laser can reshape the exposed cornea. After laser application, the epithelial flap is laid over the corneal bed and a bandage soft contact lens put on top. A Florida surgeon said, “I do mostly LASEK. I find that safer and the quality of vision better, with less dry eye. LASEK appeals to a lot of patients.”

REFRACTEC’S Conductive Keratoplasty (CK)

Most doctors are taking a cautious approach to CK. A California doctor said, “I absolutely don’t believe in it.” A Florida doctor said, “I’m waiting on that. I heard it can induce astigmatism.” Another doctor said, “It is available, but I’m still doing surface laser. I think surface ablation is safer.”

Only three sources are doing or plan to start CK, but none are huge fans. A Michigan doctor said, "I'm doing CK mostly in presbyopic emmetropes for monovision." A Texas doctor said, "I'm doing some CK for over-40 presbyopes. It doesn't last forever." Another doctor said, "I just bought a unit, and I will start in a couple of weeks. I'll use it for presbyopes – and I expect to do a lot of them."

EYEONICS' Crystalens

Even fewer sources are interested in Crystalens, the first accommodative intraocular lens (IOL). Crystalens is designed to restore both near and far vision. It is a modified plate haptic lens with hinges connecting two plates on the sides of the lens. The lens and plate parts are made of silicone and are held in the eye by plastic loops.

- Harmon said, "Part of the slow uptake of Crystalens has to do with the roll-out...The company is trying to roll it out to doctors who are committed and will promote it...Plus it is very expensive; some doctors are charging \$10,000 for a bilateral procedure, and that limits the appeal as well...Other people say, 'Let's wait for the next version from Company A'...The Crystalens proponent numbers are small, but they are growing...The company is doubling volume almost every quarter."
- A California doctor said, "I tell patients the technology is interesting, but I don't think it is ready for prime time yet. It is a 4.5 mm optic, so you will have problems with young people at night."
- A Texas user said, "Crystalens is filling a wonderful niche for 40+ patients whether they have cataracts or not for refractive lens exchange. I haven't used the AMO Array since I started doing Crystalens. I find Crystalens more 'people pleasing.'"
- A Florida doctor said, "The biggest problem is that it is not available for patients with Medicare, and it has a small optical zone. I'm usually an early adopter, but the cost is \$16,000 for doctors to participate, and it is only available for self-pay patients without insurance. It's hard to convince patients to pay for this."
- Another surgeon said, "I'm waiting to see more results. I'm not 100% comfortable with it yet."

Refractive Lens Exchange (clear lens exchange)

Half these doctors are doing refractive lens exchange, most commonly with the AMO Array, but also with the Staar Toric, the Staar Collamer, or the Alcon AcrySof. However, this remains a very niche procedure. A West Coast doctor said, "I'm using foldable acrylics, not multifocals. I don't think the quality of the AMO Array is there. Allergan is working on a hydrogel that is exactly the same size as a natural, native lens. That is about three years away, and it is really exciting. Right now, I'm banking the patients and saying, 'Not yet.' I don't need the problems or the grief."

Other doctors are excited about Alcon's ReSTOR lens. A Florida surgeon said, "ReSTOR is very exciting...They won't charge doctors \$16,000 to participate (the way Eyeonics does for Crystalens), but even \$800 for a lens would mean you can't use it in standard cataract patients."

Other Products

- **ADDITION TECHNOLOGY'S Intacs.** These corneal spacer inserts (rings) didn't catch on for correction of mild myopia, but a few doctors said they have started using more Intacs lately, particularly for keratoconus patients. The sales numbers are still fairly small, but they are growing. A Florida doctor said, "The only treatment for keratoconus is a corneal transplant or contact lenses, but Intacs are an in-between stage...Intacs got a new life for therapeutic reasons."
- **Riboflavin and ultraviolet light (UVA).** Combining riboflavin and UVA can promote corneal collagen crosslinking, which, in turn, may halt the progression of keratoconus. The riboflavin is applied topically (eye drops), followed by exposure to UVA for about 30 minutes. At least two companies are working on products in this area.

MISCELLANEOUS

There has been some discussion in refractive surgery circles recently about the lack of ANSI, ISA, or other engineering standards for excimer laser calibration. A surgeon said, "There is also no cross-platform calibration comparison or reference between laser systems. I think this is intolerable. When you go to a hardware store to buy a ¼ inch drill, you get a ¼ inch drill, and it makes a ¼ inch hole. But when it comes to excimers, no such luck. Our profession would definitely benefit if we had an independent reference lab with a protocol for calibrating laser treatments that was not funded by the manufacturers or others with vested interests. We might hire a few optical engineers and bench-testing experts to design such a system...The lasers currently in wide use calibrate on flat plastic, not on curved surfaces like the corneas we treat. This is a big source of calibration error and treatment error." ♦